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Paired tumor biopsy analysis and safety data from a pilot study evaluating Tremelimumab - a monoclonal antibody against CTLA-4 - in combination with ablative therapy in patients with hepatocellular carcinoma (HCC)

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Background

Tremelimumab is a fully human monoclonal antibody that binds to CTLA-4 expressed on the surface of activated T lymphocytes and results in inhibition of B7-CTLA-4-mediated down regulation of T cell activation. Both transcatheter arterial chemoembolization (TACE) and radiofrequency ablation (RFA) have been shown to induce a peripheral immune response which may enhance the effect of anti-CTLA4 treatment in patients with advanced HCC.

Methods

Patients with HCC (Childs Pugh A/B7; Barcelona Clinic Liver Cancer Stage C; ECOG 0/1; previously progressed on Sorafenib) are being enrolled in a pilot study of Tremelimumab at 2 dose levels (DL1 and DL2) until disease progression (irRECIST). Subtotal TACE or RFA is performed during study week 6 with DLT evaluation period encompassing first 8 weeks of study. Tumor tissue is collected for analysis at baseline on all patients with optional on-treatment tumor biopsies performed at the time of the radiologic procedure.

Results

11 pts have been treated so far, 6 pts at DL1 and 5 pts at DL2; M:F 9:2; Median age = 54(range 42-75); Cirrhosis present in 7pts. Hepatitis B/C/neg: 3/6/2. 4 pts received TACE, 7 underwent RFA during week 6 of Tremelimumab therapy. Tumor tissue is being collected for analysis at baseline in all patients. Once DL1 was established as safe and feasible on-treatment tumor biopsies are being performed at the time of the radiologic procedure (Day 36 +/- 96hrs) on all patients. So far 2 of 5 patients treated at DL2 have shown extensive immune cell infiltration on tumor biopsies after 6 weeks of Tremelimumab. More in depth analysis are currently being conducted and will be presented together with safety data.

Conclusions

Tremelimumab in combination with TACE or RFA in patients with advanced HCC is feasible. Preliminary pathology data will be presented regarding all post-treatment tumor biopsies.

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